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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,952	12/18/2001	Paul R. Ervin JR.	4273.3USW1	5284

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	4

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,952	ERVIN, PAUL R.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The response filed on August 8, 2003 (Paper No. 10) to the restriction requirement of July 2, 2003 has been received. Applicant has elected Group III, claim 7 for examination with traverse. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a).

Claims 1-10 were cancelled.

Claims 11-15 were added and are currently under consideration.

Specification

The specification is objected to on pages 2-3,7 for missing ATCC information. To be fully responsive to this Action, applicant, in responding, should supply the missing information.

The brief description of the figures on page 4 is objected to because although there is a description of Figures 1A and 1B, there is no description of "Figure 1" itself.

The specification is further objected to for improper disclosure of amino acid and or polynucleotide sequences without a respective sequence identifier, i.e. a SEQ ID NOs:. While it appears that SEQ ID NO:1 (MammA), SEQ ID NO:2 (MammB), SEQ ID NO:3 (MammC), and

SEQ ID NO:4 (ECGI nucleic acid) have been correctly identified (page 7), the specification does not appear to have supplied and or entered the necessary sequence identifiers for the following: **28SmRNA and Hip55 (page 19 and Table 2), putative amino acid sequence for ECGI in Table 3, and putative MammC amino acid sequence in Table 4.** If applicant has supplied the necessary CRF, applicant need only amend the specification to insert the corresponding sequence identifiers. Otherwise, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). *Failure to supply the appropriate sequences identification numbers in response to this action will be considered non-responsive.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-15 are rejected as indefinite in the use of antibody 7G6 as a means of identifying the claimed growth inhibitory protein. The use of laboratory designations only to identify a particular antibody renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct antibodies. For example, Wiersma *et al.* (Eur J. Immunol. 1991, Vol. 21. No. 10, abstract) teaches that the monoclonal antibody

7G6 also recognizes complement receptors in mice. Amendment of the claims to include the depository accession number of the mAb or hybridoma is required, because deposit accession numbers are unique identifiers which unambiguously define a given hybridoma and/or monoclonal antibody.

Claims 11 and 15 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a direct step for identifying the growth inhibitory protein such as by antibody binding. In other words, the mere analysis of body tissue or fluid for the presence of the protein does not adequately describe the steps of the claimed method.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **11-15** are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials (antibody 7G6) is (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

Applicants' referral to the company (Neomarkers, Freemont, CA) which carries the 7G6 antibody on page 5 of the specification is an insufficient assurance that all of the conditions of 37

CFR sections 1.801 through 1.809 have been met. Further, a review of the company's index of available antibodies at http://www.labvision.com/ did not reveal the antibody 7G6.

Thus, it is unclear if a cell line which produces an antibody having the exact structural and chemical identity of antibodies selected from the group consisting of **7G6,** are known and publicly available, or can be reproducibly isolated without undue experimentation. Clearly, without access to the hybridoma cell lines producing said monoclonal antibodies, it would not be possible to practice the claimed invention. Therefore, suitable deposits for patent purposes are required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

Furthermore, any future amendment to the specification that discloses cells which produce said monoclonal antibodies (i.e. specifically deposited hybridomas) must make sure that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository **is required**. This requirement is necessary when deposits are made under the provisions of the Budapest

Treaty as the Treaty leaves these specific matters to the discretion of each State. **Additionally, amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.**

In view of the above, it would require undue experimentation to reproduce the claimed antibodies of 7G6. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

Claims 11-15 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth analyzing body tissue or fluid for the presence of a prostate, colon, or ovarian growth inhibitory protein which comprises a polypeptide encoded by SEQ ID NO:4. Therefore the written description is not commensurate in scope with the claims broadly drawn to analyzing body tissue or fluid for the presence of prostate, colon, or ovarian growth inhibitory protein wherein the protein has a molecular weight of approximately 50-60 kDa; is recognized by antibody 7G6, has prostate, colon, or ovarian growth inhibitory activity; and produced by normal prostate, colon, or ovarian cells, but not by prostate, colon, or ovarian cancer cells.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of SEQ ID NO:4, the skilled artisan cannot envision the detailed *structure* of the multitude of proteins which may or may not be encompassed by the claimed method. Many proteins (known or unknown) may have the exact same characteristics as claimed by applicants and conception of such proteins is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a *potential* method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, the instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of inhibitory proteins. For example, the claims include the functional limitation that the inhibitory protein has growth inhibitory activity in prostate, colon, or ovarian cells. However, it is not clear that all such inhibitory proteins encompassed by the claimed characteristics have such inhibitory activity nor is it clear that the inhibitory activity of one species of said proteins (i.e. prostate ECGI, page 17) has growth inhibitory activity because it has not been demonstrated that the inhibitory activity is due to the presence of the protein. For example, the specification teaches that that the growth of cancerous prostate cells (i.e. LnCap cells) is inhibited by the addition of *normal* prostate

medium. However, one cannot extrapolate the teachings of the specification to the scope of the claims because it has not been shown that a) prostate ECGI was present in the normal growth medium and b) that the presence of the prostate ECGI caused the inhibition of growth since the medium itself may contain a multitude of other factors that caused the growth inhibition. Further, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the inhibitory proteins encompassed and no identifying characteristic or property of the instant proteins are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Therefore, the structure of these elements is not conventional in the art, and one skilled in the art would therefore not recognize from the disclosure that applicant was in possession of the genus of inhibitory proteins with the claimed characteristics.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the claiming of non-specific characteristics is insufficient to describe the genus of encompassed proteins. Therefore, only analyzing body tissue or fluid for the presence of a prostate, colon, or ovarian growth inhibitory protein which comprises a polypeptide encoded by SEQ ID NO:4, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
October 14, 2003